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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,121	01/18/2002	Randolph M. Howes	2514-0051-01	7866
22852	7590	07/15/2003		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			EXAMINER	CHOI, FRANK I
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 07/15/2003				10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,121	HOWES, RANDOLPH M.	
Examiner	Art Unit		
Frank I Choi	1616		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 April 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 5, 11, 17-28 and 30-46 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6-10, 12-16 and 29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,5,7,9</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 4/19/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-18,29-31, and 36 in Paper No. 8 is acknowledged. Examiner notes that Group I inadvertently included claim 13 which was in Group II. As such, Group I should be claims 1-12,14-18,29-31 and 36. Notwithstanding the same, Examiner expands the elected invention to include Group II, claim 13. The traversal is on the ground(s) that prosecution of all inventions and species would not constitute and undue burden on Examiner as a thorough search of the subject matter of any one group of claims would encompass a search of the subject matter of the remaining claims. Applicant has not shown that this is the case. For instance, a search of claims 37-46 would not necessarily encompass the subject matter of the other claims as the fluid does not even have to be a hypochlorite or peroxide and there is no disease state or condition or other process of using to disinfect an inert object or

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associated with claims 37-46, and the device contains other components which are not required by the other claims. Similarly, claims 1-12,14-18,29-31, and 36 require the search of methods of treating mammals whereas the other claims do not require search of methods of treating mammals. With respect to the election of species requirement, contrary to Applicant's arguments, prosecution of all species would constitute an undue burden as Applicant's claims source of peroxides and hypochlorites encompass a wide variety of different species, for instance, hydrogen peroxide, alkyl hydroperoxides, metal peroxides, metal hypochlorites, hypochlorous acid, chlorine dioxide and superoxide. Further, the method claims encompass a wide variety of different target sites, for instance, tumors, atherosclerotic plaques, pathogenic infestations, inert areas. As such, a search of all species would constitute an undue burden on Examiner. Applicant's election of tumor, sodium hypochlorite and hydrogen peroxide is acknowledged.

Accordingly, Claims 1-4, 6-10, 12-16, 29 will be prosecuted to the extent they read on the elected invention with claims 5,11,17-28, 30-46 being withdrawn as directed to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morrow (US Pat. 5,674,537).

Morrow expressly discloses singlet oxygen falling within the scope of applicant's claims (Column 1, line 64, Column 2, line 12, Column 4, lines 65-68, Column 5, lines 1-3).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (in product-by-process claims, patentability of a product does not depend on its method of production); In re Brown, 173 USPQ 685, 688 (CCPA 1972) (where the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith).

Claims 1-4, 6-10, 12-16, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrow (US Pat. 5,674,537) in view of Beattie et al. (US Pat. 5,364,344).

Morrow teaches the use of sodium hypochlorite, hydrogen peroxide and singlet oxygen for treatment of tumors which can be injected and that moderating or neutralizing amounts of

antioxidants or reducing agents may be coadministered (Column 1, lines 35-68, Columns 2-9, Column 10, lines 1-38.

Beattie et al. teach the use dual lumen catheters for delivering different fluids into the blood stream (See entire document).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of sodium hypochlorite and hydrogen peroxide to treat tumors. However, the prior art amply suggests the same as it is known in the art that hypochlorites and peroxides are effective in treating tumors. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be effective in treating tumors. Also, one of ordinary skill in the art would expect that that dual lumen catheters could be used to effectively administer different agents including active agents and moderating agents. Further, one of ordinary skill in the art would expect that simultaneous or sequential administration would be effective in treating tumors. See *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) (obvious to reverse order of prior art process steps); See also *In re Burhans*, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

July 11, 2003



JOHN PAK
PRIMARY EXAMINER
GROUP 1600